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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/780,155

02/17/2004

Wei-Kung Wang

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EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3735

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/780,155	<b>Applicant(s)</b> WANG ET AL.	
	<b>Examiner</b> KAREN E. TOTH	<b>Art Unit</b> 3735	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19 and 23-27 is/are rejected.
- 7) ☒ Claim(s) 18, 21 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has not disclosed how one would use the present application to monitor a current signal that is not the current signal generated by the moving hydrogen ions, nor has applicant disclosed any apparatus for doing so.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30 and 31 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 is directed to an "artificial machine". It is not clear how a machine can be artificial. For the purposes of examination, the claim will be treated as though it refers to a "machine".

3. Claim 31 is further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's specification discloses a "microcirculation" as being found in natural tissues and a part of blood flow; however, claim 31 depends from claim 30, which establishes the target solution as being in an "artificial machine". The target solution cannot be both in an artificial machine and in natural tissue.

***Claim Rejections - 35 USC § 101***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 33-37 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 33 is directed to an interface between an electrode and "a body"; the human body may not be claimed. For the purposes of examination, the claim will be treated as though the interface is between an electrode and a target.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki (US Patent 6416503).

Regarding claim 1, Suzuki discloses an apparatus for selectively moving hydrogen ions in an organism comprising an electrical field generator switching faster than 1 ms (1 kHz) (figure 1; column 7, lines 64-67) and a low impedance electrical connection device for introducing the field into a target (column 2, lines 32-37). The examiner notes that, though the claim calls for a "low impedance" device, Applicant has not provided any limits as to what constitutes "low" impedance, and, as such, any connection device may be considered to be low impedance.

Regarding claims 24-27, Suzuki further discloses a low pH ingredient in the connection device, such as lactic or acetic acid (column 5, lines 61-65).

7. Claims 1, 3, 5, 7-10, 12-15, 18-19, and 33-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Palti (US Patent Application Publication 2004/0068296).

Regarding claims 1, 3, and 12 Palti discloses an apparatus for selectively moving hydrogen ions in an organism comprising an electrical field generator switching faster than 1 ms (1 kHz) and an electrical connection device for introducing the field in a target

(paragraphs [0028], [0055]-[0056], [0060], [0066]-[0071]). The examiner notes that, though the claim calls for a "low impedance" device, Applicant has not provided any limits as to what constitutes "low" impedance, and, as such, any connection device may be considered to be low impedance.

Regarding claim 5, Palti further discloses generating heat (paragraph [0016].

Regarding claim 7, Palti further discloses applying an alternating field (paragraph [0068]).

Regarding claims 8 and 9, Palti further discloses a plurality of electrodes (elements 230). Since Applicant has not disclosed what the particular electrodes are "smaller" than, Palti's electrodes can all be considered to be of "smaller" area.

Regarding claim 10, Palti discloses placing an electrode on the target (figures 11, 14).

Regarding claims 13 and 14, Palti further discloses the connection device comprising a plurality of pairs generating electrical fields across the target (figures 11, 14).

Regarding claim 15, Palti further discloses the target being a tumor (paragraph [0021]).

Regarding claim 18, Palti further discloses activating electrode pairs at different times (paragraph [0089]).

Regarding claim 19, Palti's electrical field is inherently comprised of vectors, since the signals have magnitude and direction; when directed at a target (paragraph [0085]), a plurality of the signals would therefore add in terms of vector.

Regarding claims 33-37, Palti discloses an interface medium located between an electrode and its target, where the electrodes are located on an outer surface of a patient and the target is internal (figure 7). The area between the abdominal cavity and outer skin surface inherently contains low pH components, including organic acids like lactic and acetic acid, which are common cellular byproducts.

8. Claims 1 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Kirsten (US Patent Application Publication 2005/0252607).

Regarding claims 1 and 28, Kirsten discloses an apparatus for selectively moving hydrogen atoms in an aqueous solution to reduce the viscosity of the solution (paragraph [0026]) comprising an electrical field generator switching faster than 1 ms (paragraph [0023]), and an electrical connection for introducing the electrical field in a target (paragraph [0019]). The examiner notes that, though the claim calls for a "low impedance" device, Applicant has not provided any limits as to what constitutes "low" impedance, and, as such, any connection device may be considered to be low impedance.

9. Claims 1 and 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Wittle (US Patent 6877556).

Regarding claims 1 and 28, Wittle discloses an apparatus for selectively moving hydrogen atoms in an aqueous solution to reduce the viscosity of the solution (column 2, lines 18-30) comprising an electrical field generator switching faster than 1 ms

(column 3, lines 48-51), and an electrical connection for introducing the electrical field in a target (column 3, lines 1-3). The examiner notes that, though the claim calls for a "low impedance" device, Applicant has not provided any limits as to what constitutes "low" impedance, and, as such, any connection device may be considered to be low impedance.

Regarding claims 29 and 30, Wittle further discloses the apparatus being used in a tube (element 13) that is part of a machine (figure 2). Since Applicant has not defined what the tube is "small" in relation to, any tube may be considered "small."

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1, 2, 4, 7, 11, 17, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herbst (US Patent 6029090) in view of Suzuki.

Regarding claims 1, 2, 4, and 17, Herbst discloses an apparatus for selectively moving hydrogen ions in an aqueous solution comprising an electrical field generator (column 1, lines 24-34; element 10), a low impedance electrical connection device for introducing the field into a target (elements 30), a monitor for measuring variations in an applied current (column 9, lines 44-47), and means for determining a pH value from the generator's current (column 2, lines 27-30; column 3, lines 33-40). Herbst discloses the



generator providing a field that switches, but does not disclose a particular switching rate. Suzuki teaches a system for providing an electrical field to a target where the field switches faster than 1 ms (), in order to provide effective stimulation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Herbst and configured the field to switch faster than 1 ms, as taught by Suzuki, in order to provide effective stimulation. The examiner notes that, though the claim calls for a "low impedance" device, Applicant has not provided any limits as to what constitutes "low" impedance, and, as such, any connection device may be considered to be low impedance.

Regarding claims 7 and 11, Herbst further discloses generating an alternating field comprising a biphasic square wave (column 4, lines 47-54).

Regarding claim 32, Herbst further discloses measuring temperature with electrodes (column 9, lines 44-54).

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki in view of Hedgecock (US Patent 6830550).

Suzuki discloses all the elements of the claimed invention, as described above, except for the electrical field generator generating a step field. Hedgecock teaches an apparatus for providing electrical stimulation to a target comprising an electrical field generator that generates a stepped field (column 5 line 60 to column 6 line 10). It would have been obvious to one of ordinary skill in the art at the time the invention was made

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to have made the system of Suzuki and generated a stepped electrical field, as taught by Hedgecock, in order to controllably deliver stimulation.

13. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki in view of Buchner (US Patent 6745078).

Suzuki discloses all the elements of the claimed invention, as described above, except for the target comprising a region of poor blood circulation. Buchner teaches using electrical stimulation to increase blood flow in areas of poor circulation (column 2, lines 10-12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used Suzuki on an area of poor blood circulation, as taught by Buchner, since the use of electrical stimulation to increase blood flow is well known in the art.

14. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palti in view of Spiegel (US Patent Application Publication 2003/0093028).

Regarding claim 23, Palti discloses all the elements of the claimed invention, as described above, except for using a magnetic field generator to generate the electrical field. Spiegel teaches a magnetic field generator that is used to generate an electrical field for the movement of hydrogen ions, in order to efficiently generate the field. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Palti with a magnetic field generator, as taught by Spiegel, in order to efficiently generate an electrical field in a target.

***Allowable Subject Matter***

15. Claims 18, 21, and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the apparatus of claim 18, including, *inter-alia*, a system for selectively moving hydrogen ions using an electrical field switching faster than 1 ms comprising an ultrasound-generating device that is used to monitor a current signal that is not the result of the moving hydrogen ions.

Herbst discloses a similar system, but does not disclose using ultrasound to monitor current.

The prior art of record fails to anticipate or make obvious the apparatus of claims 21 and 22, including, *inter-alia*, a system for selectively moving hydrogen ions using an electrical field switching faster than 1 ms that is configured to use a current supplied by the electrical field generator to determine a pH value and to calculate the possibility of a cancer based on the measured concentration of hydrogen ions.

Herbst discloses a similar system, but does not disclose using the measured concentration of hydrogen ions (that is, pH) to calculate the possibility of a cancer.

***Conclusion***

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16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patents 6653114 to Walters, 6043066 to Mangano, 5019034 to Weaver, 6542778 to Fuhr, 5899220 to Alcocer, 4115490 to Munk, 5047007 to McNichols, 6018679 to Dinh, 5499967 to Teillaud, 4662952 to Gordon, 7288062 to Spiegel, and 6561968 to Dissing, and US Patent Application 2005/0209640 to Palti, which disclose similar inventions.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/  
Primary Examiner, Art Unit 3735

/K. E. T./  
Examiner, Art Unit 3735